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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/498,104	02/04/2000	Paul M Scopton	1001.1375101	8323

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EXAMINER	
DESANTO, MATTHEW F	
ART UNIT	**PAPER NUMBER**
3763	

DATE MAILED: 11/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/498,104	SCOPTON, PAUL M	
	Examiner	Art Unit	
	Matthew F DeSanto	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-13 and 15-20* is/are pending in the application.

4a) Of the above claim(s) *18-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-13 and 15-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-5, 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Sirhan (USPN 5,984,945).

Sirhan discloses a biliary catheter comprising an elongated shaft having a proximal end, a distal end, and an injection lumen extending therethrough, a guidewire lumen extending through a distal portion of the shaft between a proximal guidewire port and a distal guidewire port, the guidewire lumen being in fluid communication with the injection lumen of the shaft, the proximal guidewire port disposed proximal of the distal end of the shaft and distal of the proximal end of the shaft, the distal guidewire port disposed at the distal end of the shaft; and a tubular member connected to the shaft, the tubular member extending proximally from the proximal guidewire port to a proximal end disposed distal of the proximal end of the shaft, the tubular member defining a

guidewire lumen extension adapted to permit the guidewire to be retracted from guidewire lumen and re-inserted therein. (Figures 6, 7-10, 15 and entire reference).

Wherein the tubular member has a distal end disposed distal of the proximal guidewire port, and where the member is disposed about the shaft, and wherein the distal end of the tubular is fluidly sealed about the shaft, and wherein a proximal portion of the guidewire lumen extension is sized to restrict flow about the guidewire disposed therein. (Figures 6, 7-10, 15 and entire reference).

Wherein the guidewire lumen extension is axially aligned with the guidewire port, and wherein the shaft of the catheter is radially shifted at the proximal guidewire port such that the guidewire may remain substantially straight through the proximal guidewire port. (Figures 6, 7-10, 15 and entire reference).

2. Claims 1-5, 7, 10-13, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Ressemann (USPN 5,281,203).

Ressemann discloses a biliary balloon catheter comprising an elongated shaft having a proximal end, a distal end, and an injection lumen extending therethrough, a guidewire lumen extending through a distal portion of the shaft between a proximal guidewire port and a distal guidewire port, the guidewire lumen being in fluid communication with the injection lumen of the shaft, the proximal guidewire port disposed proximal of the distal end of the shaft and distal of the proximal end of the shaft, the distal guidewire port disposed at the distal end of the shaft; and a tubular member connected to the shaft, the tubular member extending proximally from the

proximal guidewire port to a proximal end disposed distal of the proximal end of the shaft, the tubular member defining a guidewire lumen extension adapted to permit the guidewire to be retracted from guidewire lumen and re-inserted therein. (Figures 1-3 and entire reference).

Wherein the tubular member has a distal end disposed distal of the proximal guidewire port, and where the member is disposed about the shaft, and wherein the distal end of the tubular is fluidly sealed about the shaft,

Wherein a proximal portion of the guidewire lumen extension is sized to restrict flow about the guidewire disposed therein, and wherein the guidewire lumen extension is axially aligned with the guidewire port, and wherein the shaft of the catheter is radially shifted at the proximal guidewire port such that the guidewire may remain substantially straight through the proximal guidewire port. (Figures 1-3, and entire reference).

3. Claims 1-5, 7, 10-13, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Crittenden et al. (4988356).

Crittenden et al. discloses et al. a biliary catheter comprising an elongated shaft having a proximal end, a distal end, and an injection lumen extending therethrough, a guidewire lumen extending through a distal portion of the shaft between a proximal guidewire port and a distal guidewire port, the guidewire lumen being in fluid communication with the injection lumen of the shaft, the proximal guidewire port disposed proximal of the distal end of the shaft and distal of the proximal end of the shaft, the distal guidewire port disposed at the distal end of the shaft; and a tubular

member connected to the shaft, the tubular member extending proximally from the proximal guidewire port to a proximal end disposed distal of the proximal end of the shaft, the tubular member defining a guidewire lumen extension adapted to permit the guidewire to be retracted from guidewire lumen and re-inserted therein, and further comprising a balloon and an inflatable lumen within the shaft.

Wherein the tubular member has a distal end disposed distal of the proximal guidewire port, and where the member is disposed about the shaft, and wherein the distal end of the tubular is fluidly sealed about the shaft, and wherein a proximal portion of the guidewire lumen extension is sized to restrict flow about the guidewire disposed therein.

Wherein the guidewire lumen extension is axially aligned with the guidewire port, and wherein the shaft of the catheter is radially shifted at the proximal guidewire port such that the guidewire may remain substantially straight through the proximal guidewire port, and where the tubular member has as length of approximately 5-30 cm and a heat shrink tube. (Figures 1, 7, 9, 11, 12 and entire reference).

4. Claims 1-5, 7-9, 10-13 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Horzewski et al. (4,771,777).

Horzewski et al. discloses a biliary catheter comprising an elongated shaft having a proximal end, a distal end, and an injection lumen extending therethrough, a guidewire lumen extending through a distal portion of the shaft between a proximal guidewire port (47) and a distal guidewire port (33), the guidewire lumen being in fluid

communication with the injection lumen of the shaft, the proximal guidewire port disposed proximal of the distal end of the shaft and distal of the proximal end of the shaft, the distal guidewire port disposed at the distal end of the shaft; and a tubular member connected to the shaft, the tubular member extending proximally from the proximal guidewire port to a proximal end disposed distal of the proximal end of the shaft, the tubular member (71) defining a guidewire lumen extension adapted to permit the guidewire to be retracted from guidewire lumen and re-inserted therein. (Figures 1-4 and entire reference).

Wherein the tubular member has a distal end disposed distal of the proximal guidewire port, and where the member is disposed about the shaft, and wherein the distal end of the tubular is fluidly sealed about the shaft, and wherein a proximal portion of the guidewire lumen extension is sized to restrict flow about the guidewire disposed therein. (Figures 1-4 and entire reference).

Wherein the guidewire lumen extension is axially aligned with the guidewire port, and wherein the shaft of the catheter is radially shifted at the proximal guidewire port such that the guidewire may remain substantially straight through the proximal guidewire port. (Figures 1-4 and entire reference).

Further comprising a balloon catheter with an inflatable balloon and an inflatable lumen.

Response to Arguments

5. Applicant's arguments, filed 09/04/03, with respect to Salmon et al. and Moore et al. have been fully considered and are persuasive. The 102 Rejection of Salmon et al. and Moore et al. have been withdrawn.

6. Applicant's arguments filed 09/04/03 have been fully considered but they are not persuasive, with respect to Crittenden et al.

7. With regards to Crittenden et al. not having a guidewire lumen extension being parallel and external to the shaft, the examiner points the applicant to figures 1, 7 and 10. The examiner is interpreting reference number 48 and 38 to make up the components of the guidewire lumen extension, and therefore these figures show a guidewire lumen extension being parallel and external to the shaft.

8. With regards to Horzewski et al. the examiner disagrees with the applicant with regards to the definition of external. According to *The American Heritage® Dictionary of the English Language, Fourth Edition*, external is defined as "Relating to, existing on, or connected with the outside or an outer part; exterior." The examiner therefore keeps his rejection because the tubular member 71 is "outside" the shaft, and therefore still reads on the claimed invention of the applicant.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 1-703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 1-703-872-9302 for regular communications and 1-703-872-9303 for After Final communications.

Matthew DeSanto
Art Unit 3763
November 17, 2003

BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700